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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,876	08/29/2003	Kenneth F. Bastow	5470.395	9346

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/651,876	BASTOW ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,21 and 22* is/are pending in the application.

4a) Of the above claim(s) *3,6-9 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/03 and 7/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-9, 21 and 22 are pending. Claim 22 was newly added by amendment, filed 9 February 2007. However, Claim 22 is withdrawn from further consideration by the examiner because it is drawn to a non-elected invention (i.e. 3-allyloxy-1-hydroxy-7-methoxyacridone). Therefore, Claims 1, 2, 4, 5 and 21 are examined herein on the merits for patentability. No claim is allowed at this time.

Claim Rejections - 35 USC § 102

The rejection of Claims 1, 2, 4, 5 and 21 under 35 U.S.C. 102(b) as being anticipated by the Lowden dissertation publication is hereby withdrawn by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 2, 4, 5 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Lowden dissertation publication.

With respect to claims 1, 2, 4, 5 and 21 of the instant application, the Lowden dissertation publication teaches a method of treating human cytomegalovirus (HCMV) infection, wherein said method comprises administering 1-hydroxy-3-isopropoxy-7-methoxyacridin-9(10*H*)-one (a.k.a., 1-hydroxy-3-isopropoxy-7-methoxyacridone) (abstract; page 1, lines 10-23; page 2, lines 1-3; page 4, Figure 1 and lines 1-3 and 8-10; page 5, lines 2 and 3; page 26, Figure 8, compound 4; page 37, lines 1, 5-7 and 9; page 38, Table 4, compound 4; page 40, Figure 10, compound 4; page 77, Table 8, compound 4; page 81, Table 9, ***compound 38***; page 83, last paragraph, lines 1-4; page 84, lines 1-11 and Table 10, ***active compound 38***; page 117, last paragraph, lines 1 and 2; page 118, lines 1-21; page 131, lines 14-16, 22 and 23; page 132, lines 1 and 2; page 133, last paragraph; page 135, last paragraph).

The Lowden dissertation publication does not explicitly teach an *in vivo* method of treating an HCMV infected subject (e.g., mammalian) by inhibiting HCMV replication therein comprising administering 1-hydroxy-3-isopropoxy-7-methoxyacridin-9(10*H*)-one to said HCMV infected subject in need thereof, as instantly claimed in claim 1.

However, the Lowden dissertation publication teaches an *in vitro* method of inhibiting HCMV replication by reducing HCMV plaque formation in HEL cells infected with HCMV, wherein said method comprises administering to said HCMV infected HEL

cells 1-hydroxy-3-isopropoxy-7-methoxyacridin-9(10*H*)-one (a.k.a., 1-hydroxy-3-isopropoxy-7-methoxyacridone). In addition, the Lowden dissertation publication teaches that the aforementioned *in vitro* "plaque assay is the accepted standard approach for measuring anti-HCMV activity" (page 131, lines 15 and 16).

Moreover, the instant application likewise does not appear to provide even a scintilla of *in vivo* scientific experimental data with respect to an *in vivo* method of treating an HCMV infected subject (e.g., mammalian) by inhibiting HCMV replication therein comprising administering 1-hydroxy-3-isopropoxy-7-methoxyacridin-9(10*H*)-one to said HCMV infected subject in need thereof. In fact, the only scientific experimental data provided within the instant specification appears to be based on the same in vitro plaque assay taught in the Applicant's dissertation, namely the Lowden dissertation publication. See U.S. Pre-Grant Patent Application Publication 2005/0049273, which is the published version of the instant specification (hereinafter the Bastow '273 publication) (paragraphs [0023]-[0027], [0106]-[0108], [0113] and [0114]); and the Lowden dissertation publication (page 2, lines 1-3; page 81, Table 9, ***compound 38***; page 83, last paragraph, lines 1-4; page 84, lines 1-11 and Table 10, ***active compound 38***; page 117, last paragraph, lines 1 and 2; page 118, lines 1-21; page 131, lines 14-16, 22 and 23; page 132, lines 1 and 2, page 133, last paragraph; page 135, last paragraph).

The Lowden dissertation publication teaches not only that the aforementioned *in vitro* "plaque assay is the accepted standard approach for measuring anti-HCMV activity," but also that a number of said acridone derivatives exhibit *in vitro* activity

profiles that rival HCMV drugs currently on the market and explicitly suggests that *in vivo* models should be conducted in the future with respect to activity, toxicity and routes of administration of said active acridone derivatives (page 2, lines 1-3; page 81, Table 9, ***compound 38***; page 84, Table 10, ***active compound 38***; page 131, lines 15 and 16; page 133, last paragraph; page 135, last paragraph). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to conduct *in vivo* scientific experiments comprising administering 1-hydroxy-3-isopropoxy-7-methoxyacridin-9(10*H*)-one, which is an active acridone derivative, to HCMV infected subjects (e.g., HCMV infected mammals including, mice, rats and eventually humans). One of ordinary skill in the art would have been motivated to conduct in vivo scientific experiments comprising administering 1-hydroxy-3-isopropoxy-7-methoxyacridin-9(10*H*)-one, which is an active acridone derivative, to HCMV infected subjects (e.g., HCMV infected mammals including, mice, rats and eventually humans) in need thereof, so as to determine the therapeutic efficacy of anti-HCMV activity within said HCMV infected subjects.

Response to Arguments

Applicant's Remarks, filed 9 February 2007, have been fully considered but they are not persuasive.

The rejection of Claims 1, 2, 4, 5 and 21 under 35 USC 103(a) as being obvious over the Lowden dissertation publication.

The Applicant's argue on pages 7-9 of the aforementioned Remarks that the Lowden dissertation publication provides insufficient biological activity data to support a method for treating beta Herpes virus infection by administering 1-hydroxy-3-isopropoxy-7-methoxyacridin-9(10*H*)-one. In fact, the Applicant equates it to looking for a needle in a hay stack.

The examiner respectfully directs attention to page 131, lines 15-16, of the Lowden dissertation publication where it is clearly stated, "The plaque assay is the accepted standard approach for measuring anti-HCMV activity." The examiner also directs attention to U.S. Pre-Grant Patent Application Publication 2005/0049273, which is the published version of the instant specification (hereinafter the Bastow '273 publication), paragraph [0113], where the Applicant's clearly state, "The results in FIG. 2A show the activity of [compound] 2 measured using a plaque-elimination assay. Compound 2 effectively blocked HMCV plaque formation with an ED_{50} value of 1.4 μM. **Therefore compound 2 is a selective anti-HCMV agent with activity comparable to recently reported values of clinical agents ganciclovir and cidofovir.**" [Emphasis added] Therefore, the instant specification discloses the plaque assay as a valid technique for determining the efficacy of a compound in blocking HMCV plaque formation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nathan W. Schlientz, Ph.D.
Patent Examiner
Technology Center 1600
Group Art Unit 1616

Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600
Group Art Unit 1616